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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/727,168

12/02/2003

Charlotte Moira Norfor Allerton

PC25420A

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11/16/2006

PFIZER INC.

PATENT DEPARTMENT, MS8260-1611

EASTERN POINT ROAD

GROTON, CT 06340

EXAMINER

GRAZIER, NYEEMAH

ART UNIT

PAPER NUMBER

1626

DATE MAILED: 11/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/727,168

Applicant(s)

ALLERTON ET AL.

Examiner

Nyeemah Grazier

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-8 and 10-22 is/are pending in the application.
- 4a) Of the above claim(s) 10-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-8, 16-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>8/18/06, 8/31/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION
FINAL REJECTION

I. ACTION SUMMARY

The Amendments to the Claims and Remarks submitted to the Office on August 31, 2006 has been fully considered and will be the basis of the following Action.

II. INFORMATION DISCLOSURE STATEMENT

The supplemental information disclosure statement filed on August 18, 2006 and on August 31, 2006 have been fully considered by the Examiner.

III. RESPONSE TO AMENDMENTS

A. 35 USC §103 Rejection

Applicant's arguments, see Remarks, filed August 31, 2006, with respect to 103 Rejection have been fully considered and are not persuasive.

Claims 1-8 and 15-17 stand rejected over US Patent No. 5,077,290. Claim 5 has been canceled. The instant claims have been amended wherein R2 represents C1-C6 alkyl. However, the rejection is maintained because as previously stated the "R" group on the morpholinyl ring is preferably "alkyl." See col. 2, lines 54-55. Thus, the only difference is that the morpholinyl ring may be substituted by methyl (C1 alkyl) in the instant invention, while the prior art discloses an unsubstituted morphoinyl ring. Thus, the rejection is maintained. See argument in previous action at page 7.

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Presuming that there is support in the Specification, the Applicant should amend the claim by deleting either (1) –NH₂– in the Y Markush group; or (2) deleting H as a Markush group for the variable R1 to obviate the rejection.

B. 35 U.S.C. 112 Rejection

Claims 1, 16 and 17 were rejected under 112 for the use of the term “prodrug.” The applicant’s arguments and amendments have been fully considered and are persuasive. Thus, the rejection has been obviated.

Applicant’s amendment necessitated the new ground of rejection presented in this Office Action. Accordingly, **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of

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record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

IV. REJECTION

35 USC § 103 Rejection

The following is a quotation of 35 U.S.C. § 103(a) that forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Graham v. John Deere Co. set forth the factual inquiries necessary to determine obviousness under 35 U.S.C. § 103(a). See Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966). Specifically, the analysis must employ the following factual inquiries:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

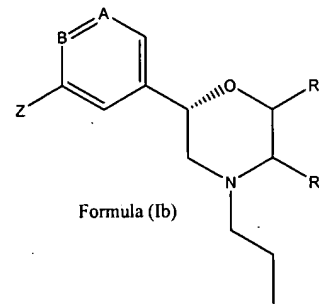
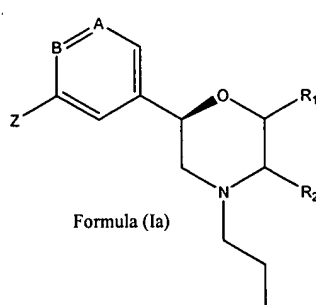
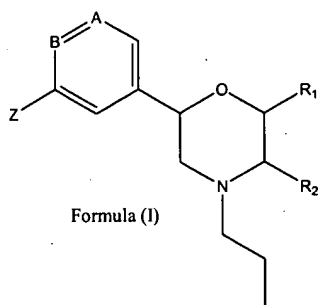
New Claims 18-22 are rejected under 35 U.S.C. § 103(a) as being obvious over FISHER, et al. US Patent 5,077,290. The instant invention of claims 18-22 is rendered obvious where one of A or B is nitrogen, and the other is CY wherein Y is NH₂ and Z is hydrogen. Claim 16 is also rendered obvious because it is well established that the substitution of methyl for hydrogen on a known compound is not a patentable modification absent unexpected or unobvious results. *See,*

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In re Wood, 199 U.S.P.Q. 137 (C.C.P.A. 1978); *See also, In re Lohr*, 137 U.S.P.Q. 548, 549 (C.C.P.A. 1963). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity.

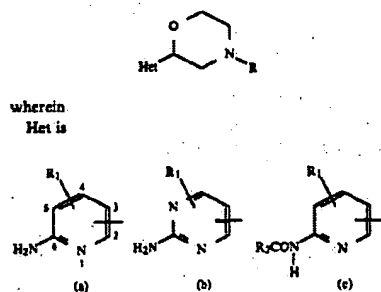
The instant inventions in Claims 18-22 recite the products of formulae (I), (Ia) and (Ib) which have utility as an agonists selective for dopamine D3 receptors over D2 receptors useful in the treatment of sexual dysfunction of male and females.

Claims 1-8, 15 and 17 are drawn to the following formulae:



Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Fisher, et al. teaches compounds and the isomeric forms of the formula (I) and there uses as growth promotants, broncodilators, antidepressants and antiobesity agents. See Fisher, et al. at



col. 11, ll. 40-42.

Ascertainment of the Difference Between the Prior Art and the Claims (MPEP §2141.02)

The difference between the prior art of *Fisher, et al.* and the instantly claimed compounds is that the *Fisher, et al.* invention, is in scope. Both the instant invention and the prior art are drawn to morpholine substituted pyridines. The difference is that the instant invention is a genus of the prior art.

Resolving Level of Ordinary Skill in the Pertinent Art

The pertinent art may be classified as medicinal chemistry and drug discovery. One of ordinary skill in the pertinent art of medicinal chemistry would have the motivation to make and use to instant invention because there is motivation to make in the instant compounds in the abovementioned references which teaches the preferred embodiments of the instant invention. The motivation to make claimed compound derives from the expectation that structurally similar compounds are generally expected to have similar properties and have similar utilities. In re Gyurik, 596 F. 2d 1012, 201 USPQ 552 (CCPA 1979).

Prima Facie Obviousness-The Rational and Motivation (MPEP §2142-2413)

The prima facie case for obviousness is derived from the preferred teaching of the references. The reference teaches preferred compounds and preferred variable substituents. In the "Detailed Description of the Invention" section of the patent application, amino substituted pyridine (formula "a") is a preferred compound. (See, *Fisher et al.*, col. 2, line 50). Also, N-lower alkyl is a preferred "R" substitution on the morpholine ring. (See, *Fisher et al.* col. 2, line 55). Thus, the teachings of *Fisher, et al.* reference would have motivated one skilled in the art to

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make and use in the instant compounds and compositions with the expectation that they would both have the same pharmacokinetic effect.

Thus, the instant invention of claims 18-22 is rendered obvious where A or B is nitrogen, and the other is CY and Y is NH₂ and Z is hydrogen. Claim 16 is also rendered obvious because it is well established that the substitution of methyl for hydrogen on a known compound is not a patentable modification absent unexpected or unobvious results. *See, In re Wood*, 199 U.S.P.Q. 137 (C.C.P.A. 1978); *See also, In re Lohr*, 137 U.S.P.Q. 548, 549 (C.C.P.A. 1963). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity.

V. CONCLUSION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nyeemah Grazler whose telephone number is (571) 272-8781. The examiner can normally be reached on Monday through Thursday and every other Friday from 8:30 a.m. - 6:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane, can be reached on (571) 272 - 0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Very truly yours,


Nyeemah Grazier, Esq.

Patent Examiner, Art Unit 1626

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